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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,449	01/09/2006	Bernd Schwenzer	101215-189	1690

27387 7590 05/02/2007

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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,449	SCHWENZER ET AL.	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,8,10,11,13-16,19-21 and 23-27* is/are pending in the application.

4a) Of the above claim(s) *13-16,19-21 and 23-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,8,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-19-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on March 20, 2007.

Currently, claims 1-2, 4, 8, 10-11, 13-16, 19-21, and 23-27 are pending. Claims 1-11 were previously examined on the merits. Applicant has cancelled claims 3, 5-7, and 9.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

Claims 1-2 and 10-11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bentwich et al. (US 2006/0257851) for the reasons stated in the Office action mailed on December 20, 2006 and for the reasons stated below.

Applicant's arguments filed on March 20, 2007 have been fully considered but they are not persuasive. Applicant argues that applicant's priority date is earlier than that

of Bentwich et al., and therefore this rejection is obviated. Applicant further contends that a certified translation of the foreign priority papers will be submitted; however, it has not been received by the Office. Since no other arguments are filed addressing the claim rejections at issue, this rejection is maintained.

New Objections/Rejections Necessitated by Amendments

Claim Objections

Claim 1 is objected to because of the following informalities: Line 9 recites "where the oligonucleotide is an antisense oligonucleotide". The term "where" is an informal language. Replacing "where" with "wherein" would be remedial. Appropriate correction is required.

Claim 4 is objected to because of the following informalities: Line 3 recites "selected from the group condisting of porous gels". It appears that the word "condisting" is a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the oligonucleotide" in line 9 and "such regions" in line 10. There is insufficient antecedent basis for these limitations in the claim. For examination purpose, "the oligonucleotide" will be interpreted as "polynucleotide", and "such regions" as "target sequence region".

Claim 2 recites "wherein the polynucleotide interacts with target sequence regions selected from the group consisting of SEQ ID NO:10 and SEQ ID NO:13" in lines 1-4. The newly entered SEQ ID NOs: 10 and 13 are found to be antisense sequences that are complementary to the target sequences SEQ ID NOs: 4 and 8, respectively. In light of this, the claim is internally inconsistent because the polynucleotide according to claim 1, which is claimed to be an antisense oligonucleotide, cannot interact with antisense oligonucleotide sequences. In other words, antisense sequences (SEQ ID NOs: 10 and 13) cannot be target sequences (SEQ ID NOs: 4 and 8) simultaneously. For the purpose of examination, claim 2 will be construed to read on a polynucleotide wherein antisense oligonucleotide sequences are selected from SEQ ID NO:10 and SEQ ID NO:13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4, 8, and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over McSwiggen et al. (US 2005/0153916 A1) in view of Vickers et al. (*The Journal of Biological Chemistry,* 2003, 278:7108-7118).

The claims are drawn to an antisense polynucleotide targeted to SEQ ID NO:4 or SEQ ID NO:8 of hTERT, wherein the antisense polynucleotide are SEQ ID NO:10 or SEQ ID NO:13, wherein the polynucleotide is immobilized on a polyacrylamide carrier, modified by phosphothioate bonds, and a composition/kit comprising the polynucleotide and a pharmaceutically tolerable carrier.

McSwiggen et al. teach an siRNA molecule targeted to SEQ ID NO:530, which comprises the entire 20 nucleotides of instant SEQ ID NO:8. See Table III. They teach that one skilled in the art can test various combinations of chemical modifications to generate nucleic acid constructs with improved stability and improved bioavailability (paragraphs 0451-0452). They also teach a composition comprising an siRNA molecule and a pharmaceutically acceptable carrier (paragraph 0162). They teach immobilizing the siRNA molecule on an agarose gel or polyacrylamide gel (paragraphs 0419, 0429).

McSwiggen et al. do not teach an antisense oligonucleotide targeted to SEQ ID NO:530, which comprises the entire length of SEQ ID NO:8.

Vickers et al. teach that the inhibitory activity, potency, efficacy, and specificity of siRNA molecules and those of antisense oligonucleotides are similar when examined in human cell culture assays. See entire reference. They teach that both siRNA and antisense oligonucleotide approaches appear to be equally valid for cell-based analysis of gene function *in vitro* (page 7117).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the siRNA molecule targeted to SEQ ID NO:530 (the entire length of instant SEQ ID NO:8) of McSwiggen et al. with the antisense oligonucleotide of Vickers et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because the entire target nucleic acid sequence of SEQ ID NO:8 claimed in the instant case was known to be a potential target sequence of the hTERT gene as taught by McSwiggen et al., and because it was known in the art that siRNA molecules and antisense oligonucleotides are functionally equivalent as taught by Vickers et al. Given these teachings, the skilled artisan would have been motivated to make an antisense oligonucleotide targeted to instant SEQ ID NO:8, thereby making an antisense oligonucleotide of SEQ ID NO:13, by targeting SEQ ID NO:530 of McSwiggen et al. Accordingly, the instantly claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Conclusion

No claim is allowed.

This application contains claims 13-16, 19-21, and 23-27, drawn to inventions nonelected with traverse in the reply filed on June 1, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

J. DOUGLAS SCHULTZ, PH.D.
SUPERVISORY PATENT EXAMINER